ERROR REPORTING AND CORRECTION

Atrium Health Wake Forest Baptist	**DOCUMENT TYPE:** Procedure	**ORIGIN DATE** 10/2020
CLIA Lab Director: Gregory Pomper, MD	**LAB DEPARTMENT:** Stem Cell Transplant and Cellular Therapy(SCTCT) Lab	**CONTACT:** Christina Warren

APPLICABLE LABORATORY(S):

☒ North Carolina Baptist Hospital (NCBH)
☐ Lexington Medical Center (LMC)
☐ Davie Medical Center (DMC)
☐ Wilkes Medical Center (WMC)
☐ High Point Medical Center (HPMC)
☐ Westchester
☐ Clemmons

PURPOSE

To describe how to consistently correct errors when they occur on reports, documents and electronic records.

SCOPE

i. Procedure owner/Implementer: Christina S. Warren/ Emily H. Wilson
ii. Procedure prepared by: Emily H. Wilson
iii. Who performs procedure: Department staff/management

DEFINITIONS

BB: Blood Bank
SCTCT: Stem Cell Transplant and Cellular Therapy
SCC: Soft Computer Consultants – Blood Bank computer system
LIS: Laboratory Information Systems
Error: any incorrectly recorded or reported information
RL6: Hospital-wide electronic event reporting system
FDA: Food and Drug Administration
N/A: Not Applicable
QA: Quality Assurance (Exception Report)

SECTIONS:

A. Manual Corrections
B. Correction of electronically reported test results / interpretations
C. Electronic Worksheet Corrections
D. Recording Corrections Made by Other Laboratories or Outside the Medical Center

POLICIES

1. Only BLACK ink will be used on manual requisitions, records, charts.
2. No gel or felt-tip pens for documenting results (Exception: Liquid nitrogen storage).
3. Ink should be indelible to the conditions with which it comes in contact.
4. No blanks should be left on labels; N/A should be used to fill label blanks.
5. No white-out or correction tape of any kind should be used to cover incorrect manual entries.
6. Changes to records shall be controlled
    - 6.1. The date of changes and the identity of the individual changing the record shall be documented, and this information shall be maintained for the retention period of the original record.
    - 6.2 Overwrites are not allowed; for example making one number into another by writing over the original information.
    - 6.2. Record changes shall not obscure previously recorded information.
        a. Manual corrections to documented results shall be made with one line drawn through the incorrect result / interpretation.
        b. Results shall not be “blacked out” or “scribbled out” with ink or marker.
        c. Correction tape or white out to cover any error shall not be used.
        d. Protocols and procedures cannot be changed except by manager or assistant manager.

7. Errors that result in a change of patient cell dosage shall be reported to the SCTCT laboratory medical director, the SCTCT Program director, and the nurse coordinators immediately.
8. Errors made by other laboratories on reports received by the SCTCT lab will be corrected by the reporting lab. SCTCT lab must document the changes made by the other laboratories.
9. An Occurrence Report and RL6 Report must be filled out and submitted to management when any electronic results are changed or corrected.
    a. Refer to Deviations, Nonconformances, Adverse Events, and Occurrence Reporting, SCT-POL-0262
    b. Refer to RL6 Reporting, BB-SOP-0077
10. Any results / interpretations that are incorrect and that reach the patient’s chart or permanent record incorrectly must be reported on an Occurrence Report and in the RL6 system when corrections and/or modifications are made.
    a. Refer to RL6 Reporting, BB-SOP-0077
    b. Refer to Deviations, Nonconformances, Adverse Events, and Occurrence Reporting, SCT-POL-0262
11. Errors involving patients and/or products will be assessed by management on a case by case basis to determine whether the incident requires FDA reporting.
12. Upon discovery, nonconforming products, components, tissue, derivatives, critical materials, and services shall be evaluated and their disposition determined.
13. Any adverse events or fatalities that occur as result of an error shall be reported to management and the department medical director. Refer to the Quality Plan Manual: There is a process that involves layers of department notification if a mortality event occurs. The laboratory medical director and laboratory administrator will be notified immediately. This notification will be escalated to the appropriate medical center departments. An RL6 will be written with appropriate harm score. The laboratory medical director will notify any outside agencies (if needed). FDA notification (if needed) will be notified as soon as possible within 7 days and a report generated within 14 days.

SECTION A: MANUAL CORRECTIONS

1. Draw a single line through the incorrect result / interpretation.

   ~~Laboratory~~

2. Document the CORRECT result / interpretation clearly above or below the incorrect result/ interpretation

   SCTCT Lab
   ~~Laboratory~~

3. Record date of correction next to the incorrect result / interpretation.

   SCTCT Lab
   ~~Laboratory~~ 8/12/23

4. Record initials of person recording error message next to the incorrect result.

   SCTCT Lab
   ~~Laboratory~~ 8/12/23 AB

SECTION B: ELECTRONIC WORKSHEET CORRECTIONS

1. Correct the electronic worksheet electronically and reprint.
   1.1 Do not destroy the original worksheet.
2. Circle the corrected result on all copies.
3. Record the message: Corrected Results, See Error Results on the Corrected Report.
4. Record the message: Error Results, See Corrected Results on the Incorrect Report.
5. Record date of correction.
6. Record initials of person recording corrected result message.
7. Complete Occurrence Report explaining the reason for the correction.
8. When results are charted, complete an RL6 report.

SECTION C: RECORDING CORRECTIONS MADE BY OTHER LABORATORIES OR OUTSIDE THE MEDICAL CENTER

1. The laboratory that had the error will enter a corrected report according to their procedure.
   1.1 Do not destroy any original reports.
2. Circle the corrected result on all copies.
3. Record the message: Corrected Results, See Error Results on the Corrected Report.
4. Record the message: Error Results, See Corrected Results on the Incorrect Report.
5. Record date of correction.
6. Record initials of person recording corrected result message.
7. Complete QA Exception Report explaining the reason for the correction.
8. When results are charted, complete an RL6 report.

LITERATURE REFERENCES:

21 CFR 211.194
FACT Cellular Therapy Standards, Revised periodically

RELATED PROCEDURES/POLICIES IN NAVEX: N/A

ATTACHMENTS/LINKED DOCUMENTS IN TITLE 21: N/A

Deviations, Nonconformances, Adverse Events, and Occurrence Reporting, SCT-POL-0262
RL6 Reporting, BB-SOP-0077

REVISION DATES: REVIEW CHANGE SUMMARY AS REPRESENTED IN TITLE 21.